K033192

DEC 2 2 2003

IOMED

SUMARY OF SAFETY AND EFFECTIVENESS
Iontophoresis Electrode
Date of Summary: September 29, 2003

A. General Provisions

Submitter's Name:	IOMED, Inc.
Submitter's Address:	2441 South 3850 West, Suite A Salt Lake City, UT 84120-9941
Contact Person:	Curtis Jensen Quality and Regulatory Manager
Classification Name:	Iontophoresis Device 21 CFR 890.5525
Proprietary Name:	RH-950
Common Name:	Iontophoresis Drug Delivery Electrode

B. Name of Predicate Device(s)

- Iontophoresis Device: K031115
  Iontophoresis Drug Delivery Electrode
  IOMED, Inc. RH-900
- Iontophoresis Device: K990318
  Iontophoresis Drug Delivery Electrode
  Birch Point IontoPatch

C. Device Description

An iontophoresis device is intended to use a direct current to introduce ions of soluble salts or other drugs into the body for medical purposes. Iontophoresis technology is based on the principle that an electric potential will cause ions in solution to migrate according to their electrical charges. The quantity and distribution of a drug delivered into and across the skin by iontophoresis is dependent on the charge and molecular weight of the ion, the strength of the electrical current applied, electrode composition, duration of current flow, and numerous other factors.

The IOMED, Inc. RH-950 iontophoresis electrode patch consists of an active delivery electrode and a passive return electrode. These electrodes are designed for a single-patient, one-application use.

This electrode is powered by an on-board 1.5-volt button-cell battery. The maximum allowable electrical current is controlled by means of a fixed in-series resistor

included in the device, while the treatment duration is pre-defined and controlled by a printed conductive ink limit switch.

The RH-950 iontophoresis electrode consists of dry, monolithic, impregnated polyester nonwoven fabric drug and electrolyte containment pads designed to be hydrated with aqueous solutions of the drug and electrolyte immediately prior to use. It features a Silver-based metallic conductive current distribution component and a medical-grade pressure sensitive adhesive tape border for skin attachment. All components in contact with the skin are known GRAS materials and/or are listed in the National Formulary.

D. Intended Use

Iontophoretic drug delivery electrodes are indicated for the administration of soluble salts or other drugs into the body for medical purposes as an alternative to hypodermic injections. They are also indicated for iontophoretic dermal administration of IONTOCAINE® (Lidocaine HCl 2% and Epinephrine 1:100,000 Topical Solution).

E. Drug Delivery and Biocompatibility

Drug Delivery

Iontophoretic transport with the IOMED, Inc.RH-950 electrode of both negative and positive charged drugs was compared to transport with Iomed's RH-900 electrode in hairless mouse skin *in vitro* by methods described by Petelenz et al., *J Controlled Release* 20 (1992), 55-56 (see 'Performance' section of this document). Model drugs used for these comparisons were dexamethazone sodium phosphate (-) (corticosteroid) and lidocaine hydrochloride (+) (local anesthetic). The testing shows that these model drugs can be comparably delivered using the RH-950.

Biocompatibility

Primary dermal irritation studies were carried out in rabbits in accordance with FDA regulations for Good Laboratory Practices (GLP) using physiological saline. The protocol was designed according to ISO 10993-10:2002, and the device was tested from both positive and negative polarities.

The results of the testing showed that the RH-900 was rated negligible when operated from the negative polarity (0.1) as well as from the positive polarity (0.3). These scores are based on the following scale:

- 0.0 to 0.4: negligible
- 0.5 to 1.9: slight
- 2.0 to 4.9: moderate
- 5.0 to 8.0: severe

These scores are comparable to the IOMED, Inc. RH-900 electrode. Similar scores from the Birch Point device are not available for comparison.

The materials in the RH-950 are identical to the IOMED, Inc. RH-900, and the cytotoxicity results of both devices will be the same. Test results on the RH-900 showed a cytotoxic grade of 2 (on a 0 to 4 scale). This indicates 'mild' reactivity. This meets USP and ISO 10993-10 requirements and shows that all the materials used in the RH-950 are safe to come in limited contact with intact patient skin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 2 2003

Mr. Curtis Jensen
Quality and Regulatory Manager
Iomed, Inc,
2441 South 3850 West, Suite A
Salt Lake City, Utah 84120

Re: K033192
Trade/Device Name: RH-950 Iontophoretic Drug Delivery Electrode
Regulation Number: 21 CFR 890.5525 (a) and (b)
Regulation Name: Iontophoresis device
Regulatory Class: II and III
Product Code: KTB, EGJ
Dated: September 29, 2003
Received: October 3, 2003

Dear Mr. Jensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act), as long as you comply with all of the Act's requirements relating to drugs labeled or promoted with the devices as described below. You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Our substantially equivalent decision does not apply to drugs for use with your device. Therefore, you may neither label nor promote your device for use with specific drugs other than Iontocaine (Lidocaine HCl 2% and Epinephrine 1:100,000 Topical Solution), nor package drugs with your device prior to FDA having approved the drugs for iontophoretic administration. For information on the requirements for marketing new drugs, you may contact:

Director
Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland

As you are aware, iontophoresis devices that are intended to use a direct current to introduce ions of soluble salts or other drugs into the body and induce sweating for use in the diagnosis of cystic fibrosis or for other uses, if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug, were classified into Class II. An iontophoresis device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body for medical purposes other than those specified for class II devices is classified into Class III (21 CFR 890.5525). We published our strategy for calling for premarket approval (PMA) applications in the enclosed Federal Register, dated May 6, 1994, and the enclosed memorandum, dated April 19, 1994, and the enclosed Federal Register, dated August 22, 2000.

If you have any questions regarding this letter, you may contact:

Kevin Lee, M.D.
Food and Drug Administration
Center for Devices and Radiological Health
Division of General, Restorative and Neurological Devices
9200 Corporate Boulevard (HFZ-410)
Rockville, Maryland 20850
(301) 594-1296

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation, please contact the Office of Compliance at (301) 594- 4659. Also, please note the regulation entitled,

"Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Indications for Use

Applicant: Iomed, Inc.

510(k) Number (if known): K033192

Device Name: RH-950

Indications For Use: Iontophoretic drug delivery electrodes are indicated for the administration of soluble salts or other drugs into the body for medical purposes as an alternative to hypodermic injections. They are also indicated for iontophoretic dermal administration of IONTOCAINE® (Lidocaine HCl 2% and Epinephrine 1:100,000 Topical Solution).

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K033192